

510(k) SUMMARY

BARRIER® EasyWarm® Active Self-Warming Blanket

This 510(k) summary information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

Date Prepared: October 15, 2013

Applicant: Mölnlycke Health Care US, LLC
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Trade/Proprietary Name: BARRIER® EasyWarm® Active Self-Warming Blanket

Common Name: Warming Blanket

Regulation Name: Thermal Regulating System

Device Class: Class II

Regulation Number: 21 CFR 870.5900

Product Code: DWJ

Predicate Device Name(s): HotDog Patient Warming System (K112488)

Description of Device:

The BARRIER® EasyWarm® Active Self-Warming Blanket is a disposable blanket 152 x 92 cm in size. The blanket contains warming pads (or heating elements) that are contained within sealed pouches that are advantageously positioned and sewn into the blanket's fabric for appropriate distribution of heat. The device is supplied in a vacuum sealed packaging. Once the blanket is removed from its' packaging, the blanket produces heat via an exothermic chemical reaction that takes place within the warming pads upon exposure to air.

The BARRIER® EasyWarm® Active Self-Warming Blanket is intended to be used in the pre-, intra- and post-operative phases of a patient's surgical experience to maintain normothermia. The blanket provides continuous thermal coverage, affording the patient active warming up to 10 hours. The blanket is removed from packaging at least 30 minutes prior to use to initiate the warming of blanket. The blanket reaches 40 °C in approximately 30 minutes. Once the blanket is placed on the patient, it helps prevent the patient from cooling during the perioperative period. The blanket is designed to help patients maintain body temperature by decreasing cutaneous heat loss. The maintenance of normothermia is accomplished through safe administration of skin surface warming facilitated by the active self-warming blanket.

Intended Use/Indication for Use:

The BARRIER® EasyWarm® Active Self-Warming Blanket is intended to help prevent hypothermia by providing warmth to the patient during the perioperative period.

Technological Characteristics:

The BARRIER® EasyWarm® Active Self-Warming Blanket and HotDog Patient Warming System (K112488) device have similar principles of operation - to prevent or maintain normothermia.

The differences in these two products are the mechanism used to provide the heat through the blanket. The BARRIER® EasyWarm® Active Self-Warming Blanket is a disposable 152 x 92 cm blanket that produces heat via an exothermic chemical reaction initiated by exposure to air, resulting from the oxidation of iron. The chemicals are securely contained in 12 individually sealed pockets, strategically placed to provide heat to the subject for optimal thermal warming. The components of the warmers are —activated coal, clay, iron, water, salt and sodium polyacrylate.

BARRIER® EasyWarm® has no external attachments, requires no power source, is quiet, and carries no risk of "hosing" or blowing pathogens. It is available in one design with three cut-outs positioned to provide the ability to position the blanket longwise on the patient. Turning the blanket 90 degrees will allow exposure of abdomen and legs if the surgical procedure warrants this.

There is asymmetry of the heating pads to allow the blanket to provide access to one extremity while maintaining coverage of the rest of the patient. The blanket should be placed with the heating pads away from the patient.

The Active Self-Warming Blanket does not contain any novel features. Non-warming blankets of the same material have been used for more than three years and this material has been used by Mölnlycke Health Care for other applications such as surgical drapes and surgical gowns.

Evaluation of Device Performance**Bench testing:**

A series of tests and evaluations were conducted in support of the device design verification activities were completed to characterize the device with respect to the temperature achieved (maximum and minimums), temperature rise time, duration of temperatures are maintained.

Biocompatibility Evaluation:

A biocompatibility assessment was completed for the device per ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing, which included the following studies:

- Skin Irritation;
- Closed Patch Sensitization
- Cytotoxicity

Stability (Shelf-life) Testing:

Stability testing was conducted to demonstrate that the integrity of the device is maintained for the labeled shelf-life period.

Clinical Testing:

The results of from a prospective multi-center randomized controlled clinical study, conducted for the BARRIER® EasyWarm® Active Self-Warming Blanket, demonstrated that skin temperatures reached with the use of the device were safety and clinically effective at maintaining core body temperatures. The following is a summary of the primary endpoint results:

- Subjects in the BARRIER® EasyWarm® treatment arm had significantly higher perioperative core body temperature, relative to subjects in the control treatment arm;
- Subjects in the BARRIER® EasyWarm® treatment arm had a significantly lower incidence of hypothermia preoperatively, intraoperatively, and postoperatively compared with the subjects in the control treatment arm; and
- There were no serious adverse events in this clinical investigation.

In addition to the aforementioned clinical study, an independent non-interventional evaluation was performed to determine the average skin temperature range and maximum skin temperatures reached with the warming blanket. The average skin temperature range and the maximum skin temperature achieved with the use of the device are 35-36° C and 40° C respectively. The skin temperatures achieved with the BARRIER® EasyWarm® Active Self-Warming Blanket have been shown to be effective at maintaining core body temperature, with very minimal risks of causing thermal injury to the skin. Skin

temperatures not exceeding 43° C are generally considered safe for skin surface warming. The reduction in cutaneous heat loss via active skin warming techniques is the scientific principle behind the maintenance and/or management of core body temperature; most of metabolic heat is lost the through skin.

Conclusion:

Based on the performance testing, it can be concluded that the BARRIER® EasyWarm® Active Self-Warming Blanket is substantially equivalent to the HotDog Patient Warming System (K112488) predicate.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 14, 2014

Mölnlycke Health Care US, LLC
Curtis Truesdale, Director, Regulatory Affairs for the Americas
5550 Peachtree Parkway Suite 500
Norcross, GA 30092

Re: K132048
Trade/Device Name: BARRIER® EasyWarm® Active Self-Warming Blanket
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: II
Product Code: DWJ
Dated: October 15, 2013
Received: October 17, 2013

Dear Mr. Truesdale:

This letter corrects our substantially equivalent letter of November 06, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for
Bram Zuckerman, MD
Director, Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K132048

Device Name: BARRIER® EasyWarm® Active Self-Warming Blanket

The BARRIER® EasyWarm® Active Self-Warming Blanket is intended to help prevent hypothermia by providing warmth to the patient during the perioperative period.

Prescription Use X
(21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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